Diabetes distress, illness perceptions and glycaemic control in adults with type 2 diabetes

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Short Title: Diabetes distress, illness perceptions & HbA_{1c}

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Abstract

The emotional distress associated with adjusting to and living with diabetes has been termed diabetes distress. This construct is distinct from depression and has been associated with glycemic control in longitudinal analyses. However, interventions to reduce diabetes distress have failed to consistently improve glycemic control. Various illness perceptions have previously been linked with both diabetes distress and glycemic control but interrelationships between these features have not been previously investigated. We hypothesized that illness perceptions mediate the relationship between diabetes distress and glycemic control. Participants with Type 2 diabetes mellitus (DM) attending diabetes outpatient clinics (n = 84) completed the Diabetes Distress Scale 17, Brief Illness Perceptions Questionnaire and the Patient Health Questionnaire 9 as well as providing demographic and clinical information on diabetes type, duration, use of insulin, frequency of blood glucose monitoring, smoking status and number of complications. Most recent HbA_{1c} and BMI were collected from medical records. Using regression analysis we demonstrated that the illness perception of personal control, regimen-related distress, socioeconomic status and insulin use were significant contributors in the final model predicting HbA_{1c}. Higher levels of personal control were associated with improved glycemic control. Conversely, regimen related distress was associated with poorer glycemic control. Importantly, mediation analyses showed that relationship between regimen-related distress and HbA_{1c} was mediated by personal control. Therefore our work suggests that psychological interventions designed to reduce diabetes distress may be more efficacious in improving glycemic control if they address an individual's perception of personal control. Future work that attempts to delineate the relationship between

regimen-related distress and personal control will help to increase our understanding of psychological determinants of glycemic control.

Introduction

It is well established that there is an association between diabetes and depression, with estimates suggesting that up to three times as many patients with diabetes meet clinical criteria for diagnosis of depression compared to the non-diabetic population (Egede & Dismuke, 2012). However, it has recently been suggested that the understandable emotional distress specifically related to living with the demands of diabetes may account for the majority of these depressive symptoms. This has been termed diabetes distress (DD), which is defined by Fisher and colleagues (2012) as "the unique, often hidden emotional burdens and worries that are part of the spectrum of patient experience when managing a severe, demanding chronic disease like diabetes" (p. 259). DD has been conceptualised to include four domains encompassing distress related to diabetic regimen, interpersonal issues, relationships with physicians and emotional burden. Importantly, higher levels of diabetes distress have been shown to be associated with metabolic biomarkers in prospective, longitudinal analyses (Fisher et al., 2007; Fisher et al., 2010). Specifically, high scores on a validated measure of diabetes distress have been linked to high non-HDL cholesterol (Fisher et al., 2007) and poor glycemic control (Fisher et al., 2008; Fisher et al., 2010). To date, reported interventions for DD have not translated into reductions in HbA_{1c} – a biomarker commonly used as an index of glycemic control where higher levels of HbA_{1c} reflect poorer glycemic control (Fisher et al., 2013; Jones, Vallis, & Pouwer, 2015). This suggests that there may be other important psychological variables that might impact upon HbA_{1c} which have not been addressed in reported interventions.

Illness perceptions, part of Leventhal's Common Sense Model, form an important basis for understanding how individuals make sense of a chronic illness. The common sense model (CSM) suggests that when an individual is confronted with an illness or condition, they will attempt to assign meaning to this illness by accessing their perceptions about the

illness. Furthermore, the model describes a bidirectional interaction between illness perceptions and the emotional state of an individual. In an effort to restore normal functioning, individuals will develop coping strategies (based on their illness perceptions and emotional state), which will then be evaluated in terms of their success in restoring the previous state of wellbeing. The result of this evaluation may be a change in coping strategy and/or a change in perceptions about the illness. Key beliefs have been labelled as consequences (how much the illness is affecting their life); timeline (how long it will last); personal control (the degree of control they feel they have over their illness); treatment control (how helpful they think their treatment can be); identity (the degree to which they experience symptoms from their illness); coherence (how well they understand their illness); emotional representation (how affected they are emotionally); and concern (their degree of concern about their illness) (Broadbent, Petrie, Main, & Weinman, 2006).

Illness perceptions explain a significant proportion of the variance in physical and psychological outcomes in a range of illnesses including diabetes (Dempster et al., 2011; Dorrian, Dempster, & Adair, 2009; Skinner et al., 2011). A systematic review of the literature has shown that identity; consequences; timeline/cyclical; emotional representation; concern and personal control are all significantly correlated with glycaemic control. Higher levels of positive beliefs were linked to lower HbA1c and higher levels of negative beliefs were linked to higher HbA1c (McSharry, Moss-Morris, & Kendrick, 2011). Moreover, lower perceived consequences and higher personal control have been associated with adherence to insulin (Broadbent, Donkin, & Stroh, 2011) while higher identity, greater coherence and higher personal control all predicted foot care (Vedhara et al., 2014). For personal control specifically, higher levels predicted higher quality of life and exercise behavior (Steed, Barnard, Hurel, Jenkins, & Newman, 2014).

Research demonstrates that DD and a variety of illness perceptions link with HbA1c. The CSM provides an explanation for how cognitive (e.g. illness perceptions), emotional and behavioral elements interact in the context of chronic illness. The four domains of DD also involve these same elements; therefore, the CSM would predict that illness perceptions and DD might interact with one another to influence an outcome such as HbA1c. For example, items comprising the regimen distress subscale on a measure of DD typically relate to one's perception of regimen adherence and their emotions relating to same – e.g. 'feeling I am often failing with my diabetes regimen'. This also has some relationship to one's behavior. According to the CSM, endorsement of such a statement would overlap with, and influence, illness perceptions as well as the resulting health outcomes. Additionally, previous evidence shows moderate correlations between some illness perceptions and diabetes distress (Welch, Jacobson, & Polonsky, 1997).

Therefore, given the relationships between DD and illness perceptions with HbA1c, and the theoretical rationale for the interaction between DD and illness perceptions, it is important to investigate whether the relationship between DD and HbA1c might be mediated by illness perceptions. Herein, we present our findings from a cross-sectional analysis of DD, illness perceptions and HbA_{1c} in patients with Type 2 Diabetes that tests the hypothesis that the link reported between DD and HbA_{1c} is mediated by illness perceptions.

Methods

Participants and procedure

Participants were recruited through diabetes outpatient clinics in a large, urban hospital between October 2014 and January 2015. Eligibility criteria were pre-defined: age 18 or over and a definite diagnosis of diabetes for greater than one year. Eligible patients who scheduled and attended appointments in this time period were invited to participate. The researcher was present to provide assistance in completing the questionnaires if requested by

participants. Ethical approval for the study was granted by a NHS Research Ethics Committee. All participants consented to take part in the study.

Measures

All questionnaires were randomly ordered in each pack to prevent order effects.

Diabetes distress. Diabetes distress was measured using the 17-item Diabetes Distress Scale (DDS17) (Polonsky et al., 2005). DDS17 contains items producing four subscales: relationship with diabetes physician, emotional burden, regimen-related distress and interpersonal distress. Items are scored on a Likert scale from 1 (no distress) to 6 (serious distress) for experiences over the past month. Mean subscale scores of ≥3 indicate clinical distress. Internal consistency for the four subscales has been reported as .88 to .90 (Polonsky et al., 2005). Cronbach's alpha for this study was similar (emotional burden: .95; physician distress: .88; regimen distress: .88; interpersonal: .93). Factor analysis has confirmed independence of the 4 subscales (Polonsky et al., 2005) and DDS17 has been correlated with HbA_{1c} (Fisher et al., 2010). All four subscale scores are used in our analysis.

Illness perceptions. Illness perceptions were assessed using the Brief Illness Perception Questionnaire (BIPQ) (Broadbent et al., 2006). The eight illness perceptions are measured by one item each and include consequences, timeline, personal control, treatment control, identity, coherence, emotional representation and illness concern. Participants rate the strength of each belief on a 10-point Likert scale where 0 = none and 10 = complete. This scale has shown satisfactory test-retest reliability and moderate to good concurrent validity with the relative domains in the IPQ-R as well as being validated in a Type 2 DM population (Broadbent et al., 2006).

Depression. The 9-item Patient Health Questionnaire (PHQ-9) (Kroenke, Spitzer, & Williams, 2001) was used to measure levels of depression. Participants are asked to answer in regards to their experiences over the previous two weeks and respond to items using a 4-point

Likert scale where 0 is not at all and 3 is nearly every day. A cut-off score of 12 was chosen on the basis of previous analyses of people with diabetes attending outpatient clinics (van Steenbergen-Weijenburg et al., 2010). Cronbach's alpha for the current study = .92.

Demographic and clinical variables. Data for participants' most recent HbA_{1c} measurement and BMI were obtained from medical records. Participants provided information on age, gender, marital status, smoking status, duration of diabetes, number of complications, frequency of blood sugar monitoring in a typical day and whether their regimen included insulin. Diabetes type, age, gender, duration of diabetes and regimen information were obtained from or verified with medical records where information provided by participants was missing or ambiguous. Socioeconomic status (SES) was determined by using participants' postcodes to obtain a multiple deprivation measure score for their census output area.

Statistical analysis

Data for analysis were only included for participants who had complete information on all included variables. All analysis was conducted using SPSS version 21. Bivariate correlations were run for all variables with HbA_{1c}. All variables were then entered into a regression model. A backward regression model was employed to identify the most pertinent predictors of HbA_{1c}. The Baron and Kenny (1986) approach was used to check whether the relationship between diabetes distress and HbA_{1c} was mediated by illness perceptions.

Results

Participants

535 people with various types of DM attended clinics during the study period and were offered questionnaires – 176 of these individuals participated (32.9% response rate). Thirty-six participants had a diabetes type other than Type 2, 6 participants did not meet the

inclusion criteria, 2 did not complete consent forms and 48 participants provided incomplete data. This sample therefore comprises 84 participants with Type 2 DM (Table 1).

-----Insert Table 1 here-----

Means and standard deviations for the DDS17 and BIPQ subscales are in Table 2.

-----Insert Table 2 here-----

Pearson correlations for all variables with HbA_{1c} are presented in Table 3.

-----Insert Table 3 here-----

All variables were entered into a backward regression model to identify the strongest predictors of HbA_{1c} from those variables measured in the study. Table 4 provides the final model. This model explains 20% of the variance in HbA_{1c} ($F_{4, 79}$=6.19, P<.001).

-----Insert Table 4 here-----

The regression model indicates that regimen-related distress and personal control are the pertinent diabetes distress and illness perceptions variables, respectively. Therefore, the Baron and Kenny (1986) approach was used to check whether personal control mediated the relationship between regimen-related distress and HbA_{1c}. This is a 4 step approach. Step 1 is to demonstrate a relationship between regimen-related distress and HbA_{1c}. This was r = 0.300, P = .006 (see Table 3). Step 2 is to establish the presence and size of the relationship between personal control and HbA_{1c}. This was r = -.367, P = .001 (see Table 3). Step 3 is to determine the relationship between regimen-related distress and personal control. This was r = -.381, P<.001. Step 4 involves demonstrating that the relationship between regimen-related distress and HbA_{1c} decreased after personal control was introduced. We used hierarchical regression to examine this. After personal control was entered into the model, the relationship between regimen-related distress and HbA_{1c} decreased and became non-significant (standardised β = .188, P = .091), whereas the relationship between personal control and HbA1c remained (standardised β = -.296, P = .009). The Sobel test indicated that the

mediated relationship is significant (Z=2.18, *P*=.029). The mediating effect is depicted in Fig. 1.

-----Insert Figure 1 here-----

Discussion

To the authors' knowledge, this is the first study to examine the relationships between all DD dimensions, illness perceptions and HbA_{1c}. This study has yielded two key findings: firstly, DD positively correlates with HbA_{1c} in this population and, of the DD domains, regimen-related distress is most strongly associated with HbA_{1c}, a finding concordant with a recent analyses in patients with type 1 diabetes (Strandberg et al., 2015) and supported by interventional studies which have shown that reductions in regimen related distress are predictive of improved future glycemic control (Hessler et al., 2014). Secondly, the relationship between regimen-related distress and HbA_{1c} is mediated by personal control; furthermore, personal control is the strongest covariate of HbA_{1c} when accounting for DD and other clinical and demographic variables.

Our study provides evidence to suggest that the relationship between regimen-related distress and HbA_{1c} is an indirect one, mediated by personal control. Previous research linking DD to HbA_{1c} has primarily utilised the DDS17 total score (e.g. Fisher et al., 2010) rather than comparing the values of the individual subscales. Results in this sample concur with previous studies finding no strong association between depression and HbA_{1c}. Other research that addressed regimen-related distress alone also found positive relationships between it and HbA_{1c} (Cummings et al., 2014; Hessler et al., 2014; Pandit et al., 2014).

Personal control is the degree to which individuals feel they can influence the course of their illness rather than how competent they are at doing so; therefore, it is connected to, but distinct from, self-efficacy which focuses on competence. Recent research by Gonzalez et al. (Gonzalez, Shreck, Psaros, & Safren, et al., 2014), published during the course of

conducting this research, likewise found that personal control mediated the relationship between one dimension of DD (emotional burden) and HbA_{1c}. In contrast, this study considered all aspects of DD and found that emotional burden was not as important for HbA_{1c} as regimen-related distress. Additionally, this study considered all dimensions of the BIPQ rather than solely personal control. A number of previous studies have implicated personal control as important for HbA_{1c} and meta-analyses have found a small but significant association (Hagger & Orbell, 2003; McSharry, Moss-Morris, & Kendrick, 2011).

Not only do the findings here contribute to the literature on the value of personal control in diabetes, but they also help illuminate the link between DD and HbA_{1c}. The superior predictive value of personal control over all aspects of DD in this sample is interesting as previous effect sizes for personal control in relation to HbA_{1c} have been small ($r = -0.12$; McSharry et al., 2011). However, effect sizes between DD and HbA_{1c} have been similarly small ($r = .17$; Fisher et al., 2010). Our findings support a hypothesis that regimen-related distress is a manifestation of a lack of personal control in Type 2 DM; regimen distress is important, but its relationship to HbA_{1c} can be explained by the underlying belief that one cannot affect one's diabetes. Indeed, Bridges and Smith (2015) have demonstrated that personal control mediates the relationship between DD and perceptions of the doctor-patient relationship providing further evidence that some of what is conceptualised in DD may relate to an individual's sense of control.

There are a number of potentially important clinical implications from this study. These results suggest that psychological intervention with patients exhibiting moderate or high diabetes distress may be enhanced in terms of its effects on HbA1c if it addresses personal control. In fact, some interventions addressing illness perceptions generally have produced improvements in glycemic control (Keogh et al., 2011). The relative strength of the relationships between personal control, DD and glycemic control found in this study is

particularly relevant when considering why previous DD interventions (Berry, Lockhart, Davies, Lindsay, & Dempster, 2015; Fisher et al., 2013) have not produced significant improvements in HbA_{1c}.

With the burden of diabetes care falling on an increasingly time-pressured health-care system it is essential that these findings are translated into pragmatic, efficacious interventions. This study suggests that practice might be improved by engaging in a conversation about patients' perceptions of their level of control over their diabetes. A simple way to do this could be to utilise the question measuring this construct in the BIPQ – "on a scale of 1-10, how much control do you feel you have over your diabetes?" Further to this, practitioners should look to assess reasons for these beliefs and encourage reflection on their validity. Any conversation about control should helpfully focus on what patients can control (e.g. their self-management behaviours) versus what they can only influence indirectly (i.e. HbA_{1c} readings) in addition to emphasising the normal and expected variation in blood sugars.

Limitations of this study include its cross-sectional design and limited generalisability. As a cross-sectional analysis this study is primarily useful for hypothesis generating. In particular this type of analysis is susceptible to reverse causality. Indeed, our data could be interpreted as demonstrating that personal control mediates the effect of HbA_{1c} on diabetes distress – higher HbA_{1c} may impact upon one's perceptions of personal control and this may increase the distress associated with their diabetes regimen. While this is a potentially valid interpretation of the data, we find this scenario to be unlikely given that it has been shown that baseline elevations in diabetes distress predict glycemic control (Aikens, 2012; Strandberg et al., 2015) and that reductions in regimen related distress secondary to a behavioural intervention are associated with an improvement in future HbA_{1c} (Hessler et al., 2014). These considerations notwithstanding, our results should be confirmed in larger

longitudinal analyses where directionality can be more clearly inferred. In addition, participants included a complex mix of cases with a high proportion on a prescribed insulin regimen and 80% of participants above the HbA_{1c} target of 53 mmol/mol and was obtained in a secondary care setting. Therefore, practitioners should extend the recommendations made above to less complex cases with caution.

In summary, we have demonstrated that personal control mediates the effect of regimen-related distress on HbA_{1c}. This exploratory study provides a rationale for a longitudinal analysis of the inter-relationship between personal control, diabetes distress and HbA_{1c} across the range of care delivery settings. Furthermore, it justifies the design of interventional studies addressing personal control in the context of diabetes distress as a means to improve HbA_{1c} and may provide helpful insight to practitioners hoping to improve diabetes outcomes with informal psychological interventions.

Conflicts of interest

None to declare.

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333 **Figure Legend**

334 Figure 1. The mediating effect of personal control on the relationship between diabetes distress
335 (regimen-related distress) and HbA_{1c} (standardized Beta coefficients displayed).

336 **p < .01; ***p < .001

337

338

339 Table 1. Demographic and clinical characteristics of participants

Study variable	**Mean (SD) or %**
Age in years	59.3 (12.7)
Male gender	52.4%
Living alone	42.9%
Current smoker	20.2%
Body Mass Index (kg/m^2)	34.5 (6.9)
Depression	10.0 (7.6)
Duration in years	9.9 (6.6)
HbA_{1c} <53 mmol/mol (< 7.0%) 53 to 58 mmol/mol (7.0-7.5%) 59 to 63 mmol/mol (7.5-7.9%) 64 to 74 mmol/mol (8.0-8.9%) 75 mmol/mol and over (9% and over)	 20.2% 7.2% 20.3% 22.8% 29.8%
No. of complications	1.3 (1.1)
Insulin regimen used	39.3%

340

341

342 Table 2. Means and standards deviations for DDS17 & BIPQ subscales

343

DDS17	**Mean (SD)**	**Possible Range** 344
Emotional burden	2.6 (1.5)	1-6
Physician-related distress	1.6 (1.1)	1-6
Regimen-related distress	2.5 (1.3)	1-6
Interpersonal distress	2.0 (1.4)	1-6
DDS17 Total Score	2.2 (1.1)	1-6
BIPQ		
Consequences	4.5 (2.6)	0-10
Timeline	9.3 (1.7)	0-10
Personal control	5.6 (2.3)	0-10
Treatment control	7.5 (2.3)	0-10
Identity	5.0 (2.5)	0-10
Concern	6.0 (3.0)	0-10
Coherence	6.8 (2.5)	0-10
Emotional representation	5.2 (3.2)	0-10

345 Table 3. Bivariate correlations for all study variables with HbA_{1c}

Study variable	**HbA_{1c}**	***P***
Age	-.156	.156
Gender (1 = male, 2 = female)	.140	.204
Living status (0 = living alone; 1 = living with partner/spouse)	-.078	.480
SES	.186	.090
Smoking status (1 = yes, current smoker; 2 = no)	-.095	.391
Body Mass Index	.155	.160
Duration	-.099	.372
No. of complications	-.023	.837
Insulin (0 = no; 1 = yes)	.081	.463
Depression	.103	.351
DDS17		
Emotional burden	.240	.028
Physician-related distress	.150	.175
Regimen-related distress	.300	.006
Interpersonal distress	.283	.009
BIPQ		
Consequences	.104	.345
Timeline	-.109	.322
Personal control	-.367	.001
Treatment control	-.232	.034
Identity	.153	.164
Concern	.137	.215

Coherence	-.192	.080
Emotional representation	.261	.016

346

347 Table 4. Standardised beta co-efficients and *P*-values for the final regression model

348

	Standardised coefficient (β)	*t*	*P* 349
SES	.209	2.06	.043
Taking insulin vs not	.211	2.05	.044
DDS17			
Regimen-related distress	.221	2.04	.045
BIPQ			
Personal control	-.316	2.83	.006

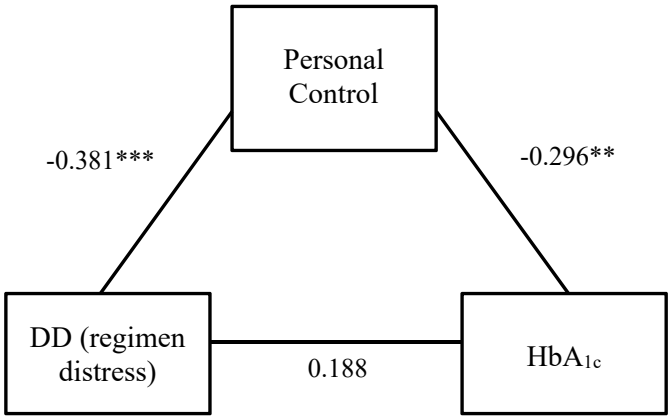

Figure 1